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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,700	BRAUN, ANDREAS	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13-20,44-53,69-71 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13-20,44-53,69-71 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed May 12, 2004. Currently, claims 1-8, 11, 13-20, 44-53, 69-71, 75 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2004 has been entered.

3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

4. Any objections and rejections not reiterated below are hereby withdrawn.

a. Upon reconsideration and applicant's arguments directed to the left ventricular function data and the mutation at position 2073, the utility and enablement rejections over the nucleic acid claims has been withdrawn. Since the polymorphism at this location appears more frequently in the GG variant, the products would be useful for detecting the nucleic acid for information about left ventricular function.

b. The rejections of Claim 75 under 102 have been withdrawn in view of the amendments to the claims to requires a "primer with a free hydroxyl for enzymatic extension through a polymorphic region of an AKAP10 gene corresponding to a position selected from the group consisting of...." Each of the rejections comprises the

polymorphic region of the recited nucleotides, thus could would not be for enzymatic extension through a polymorphic region.

Claim Objections

5. Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The scope of Claim 4 and 5 appear to be identical. SEQ ID NO: 1 and 3 appear to be identical between positions 138-2126 except for the polymorphism which is required to be a G in Claim 1 and is within SEQ ID NO: 3.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 75 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are drawn to primer comprising a sequence of nucleotides selected from the group consisting of SEQ ID NO: 8, 19, 20.

The specification teaches that AKAP10 is located on Chromosome 17, contains 15 exons and 14 exons and has been found to be responsible for the sub-cellular

localization of the camp-dependent protein kinase (page 98, lines 28-32). The art teaches the AKAP10 cDNA (D-AKAP2) in Genbank Accession Number AF037439 and NM007202 (page 41). The specification teaches the detection of a single polymorphisms within the AKAP10 protein which causes a substitution of a Ile to a Val at position 646 of SEQ ID NO: 2 and a substitution of an A to a G at position 2073 of SEQ ID NO: 1. The specification asserts that the allelic variant has been found to vary in frequency in DNA samples from younger and older segments of a healthy population (page 43, lines 5-10). The specification similarly discusses AKAP10-1 allele which is located in the 3'UTR region. The specification performed similarly studies with regard to age related polymorphisms and determined that there was a difference between the populations.

The art teaches D-AKAP2 is a novel protein kinase A anchoring protein with a putative RGS domain. The cloning of a novel AKAP which interacts with both the type I and II regulatory subunits was reported as D-AKAP2 (Huang et al. PNAS, Vol. 94, pages 11184-111889, October 1997).

The specification nor the art has taught a substantial utility for a nucleic acid variant which comprises a single nucleotide polymorphism comprising SEQ ID NO: 8, 19, 20. A substantial utility is defined as a utility that defines a "real world" us such that the utilities do not require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. The specification asserts that the nucleic acid is useful to determine increased or early susceptibility to morbidity. This

assertion is not substantial because further research to identify or reasonably confirm a "real world" context of use would be required.

The specification fails to provide any specific or substantial analysis of mutations AKAP10-1, -6 or –7. The analysis of AKAP10-1 as associated with mortality, is not persuasive for the reasons of record. The specification asserts that the nucleic acid is useful to determine increased or early susceptibility to morbidity. This assertion is not substantial because further research to identify or reasonably confirm a "real world" context of use would be required. It is additionally noted that the specification fails to study an ethnically diverse population. The specification states that only Caucasian individuals were analyzed. The skilled artisan would be required to perform additional experimentation to determine whether this particular population is representative of the entire world population or whether this was merely applicable to Caucasian individuals. The specification does not analyze individuals in a progressive study of their lifetime but rather takes a current snapshot of the percent frequencies of the particular SNP. Therefore, it is unpredictable whether the original populations of younger and older initially contained the same frequencies of alleles. If the polymorphism was regionally isolated, the event of mobility of the younger population would explain the variation of the polymorphisms within the populations. For example, if elderly Californians remain relatively settled within the region, and younger individuals migrate to the region, the frequencies of the polymorphism may vary. Without further analysis of the original older population of allele frequencies it is unclear how these frequencies have changed. In the event that the nucleotide is environmentally sensitive

and has either been selected against. Furthermore, if the polymorphism is located within a region of the gene which is a hotspot and naturally mutates in an individuals life, frequencies of the variation would change over time and would not be a reliable predictor of mortality. Additionally, whether the change is in response to certain environmental causes, the presence of a variant C allele is not predictable. The specification does not analyze individuals who are deceased for the presence of various alleles. Had the specification demonstrated that deceased individuals contained more T alleles in conjunction with the instant study illustrating that young individuals had C, a more conclusive analysis may be drawn.

The art is silent with respect to additional mutations within the subcellular localization of camp-dependant protein kinase and therefore, not well characterized as to how affect mortality or morbidity.

Additionally, there is no indication of what meant by increased mortality. The specification has defined "mortaility" as the statistical likelihood that an organism will not survive a full predicted lifespan. The specification has not provided any indication that the individuals analyzed have not survived a full predicted lifespan. Moreover, it is unclear what the relative meaning of increased mortality encompasses since all individuals are predisposed to die.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful

conclusion". Therefore, in order to reasonably confirm a "real world" context of use for this nucleic acid, the skilled artisan would be required to carry out further research.

Response to Arguments

The response traverses the rejection. The response asserts that no further research is required to identify or reasonably confirm a "real world" context of use for the nucleic acids. The response argues that AKAP10-1 alleles are markers for predicting susceptibility to morbidity and/or increased mortality and the use of polymorphic AKAP genes as markers for detecting predisposition to disease and various conditions (page 13 of response filed May 12, 2004). This argument has been thoroughly reviewed, but is not found persuasive because AKAP10-1 allele has not been associated with any specific disease or condition. It is noted that applicant's have not addressed the association of the polymorphic marker with morbidity as extensively discussed in the rejection above. There is evidence that the alleles were in the population equally prior to "morbidity" or "mortality" studies, thus, there is no evidence that the alleles are associated with morbidity or mortality, for example. The response asserts that the "allelic variants decrease with age." The study performed would not provide such information. There is no evidence that the population studied had equal numbers of variants prior to death. All that can be said is that there are less variant alleles in older populations. This does not necessarily mean that the variant was selected against, as attorney arguments suggest (see reasons above in rejection). Association of AKAP10-5 does not confer a specific and substantial utility for all AKAP10 allelic variants. Although the association data for the AKAP10-5 mutation is

associated with LV function and cardiovascular disease in males over 50, there is not specific or substantial utility for each other AKAP10 variant. The response asserts that the occurrence of these allelic variants is correlated with early death and with facilitating disease-specific susceptibility, individuals with alleles correlated with such early death are candidates for implementing a more aggressive treatment regime at disease onset. This argument has been thoroughly reviewed, but is not found persuasive because the asserted utility of "implementing a more aggressive treatment regime at disease onset" is not specific. The specification fails to provide any specific disease such that the asserted utility is not specific, but general for all mutations and variants.

The response asserts that there are a variety of method to detect the presence of allelic variants (page 16 of response filed May 12, 2004). This argument has been thoroughly reviewed, but is not found persuasive because the discussion is not directed to specific or substantial utility. The examiner acknowledges that there are many well known methods for detecting variants.

The response asserts that there is a difference between instances in which experiments or research must be done in order to ascertain a use for a product or process within stances in which a product or process is claimed that is used by a researcher conducting research (see response filed May 12, 2004, page 18). This argument has been thoroughly reviewed, but is not found persuasive because the skilled artisan would be required to perform experiments or research on the chemical compounds for each of the allelic variants to ascertain a use for the product. The

response asserts that the compounds have uses, however, the rejection above details why allelic variants such as AKAp10-1; AKAP10-6 and AKAP10-7 do not have a use.

With respect to the data for AKAP10-1 allelic variant, (see page 21 of response filed May 12, 2004), while the specification indicates that a significant number of older individuals do not have the variant, this is not a specific utility for the reasons set forth above.

The extensive discussion of case law is not repeated herein for the sake of brevity.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 75 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-2, 6-8, 11, 13-20, 44, 47-53, 69-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 19-20, 51-53 are broadly drawn to encompass a sequence of nucleotides that encodes a polypeptide as set forth in SEQ ID NO: 2. The claim does not require a nucleic acid molecule encoding SEQ ID NO: 2. The claim is broadly interpreted to encompass fragments encoding SEQ ID NO: 2 embedded within nucleic acid sequences. This genus of nucleic acids is very large and has substantial variability. Essentially, as written, the claims would encompass nearly all nucleic acid molecules.

Claims 6-8, 15-18 are drawn broadly to encompass any isolated nucleic acid which comprises at least 16, 30, or 50 contiguous nucleotides of SEQ ID NO: wherein the contiguous nucleotide include 5 contiguous nucleotides from position 2069-2077 of SEQ ID NO: 3. The claim as written minimally comprises 16, 30 or 50 contiguous nucleotides of SEQ ID NO: 3 embedded within a larger sequence. As noted by the art cited in rejections below, the instant specification has not described a representative number of members within this very large genus. There is actual reduction to practice of a single disclosed species, namely SEQ ID NO: 3. The genus of nucleic acids comprising at least 16, 30 or 50 contiguous nucleotides from SEQ ID NO: 3

encompasses splice variants of AKAP10-5, polymorphic sequences of AKAP10-5, a full length gene which contains the fragment and homologous sequences which have not been described. There is substantial variability among the species of DNA s encompassed within the scope of the claims because the claim is only drawn to a fragment of SEQ ID NO: 3 which may be embedded in alternative sequences.

Claims 11-14, 47-50, 69-71 is drawn to an oligonucleotides which comprises a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO: 1 or 3. The specification defines "adjacent" as a position 5' to the sit of a SNP such that there could be unpaired nucleotides between the position and the site of the SNP (page 40, lines 14-16). Claim 69 is drawn to a solid support comprising a nucleic acid comprising a polymorphic region of an AKAP10 gene, wherein the polymorphic region comprises a nucleotide at a position corresponding to position 2073 of SEQ ID NO: 1 that is other than an A. As defined by the specification, a nucleic acid which "corresponds" to the nucleic acid may be of different length, such that the sequences are aligned and then the position that lines up with 2073 is identified (page 38-39). This does not require any particular sequence flanking the nucleotide "other than A." The claim encompasses any size nucleotide sequence, which hybridizes under any conditions upstream of position 2073 of SEQ ID NO: 1 or 3 or any sequence which "corresponds" to position 2073. Thus, the "corresponding" sequence does not require any particular similarity or identity with SEQ ID NO: 1 or 3. Moreover, Claim 13 requires that the primer hybridize immediately adjacent to a position corresponding to a position corresponding to position

2073. As discussed above, "corresponding" does not require that the sequence resemble SEQ ID NO: 1 or 3. Moreover, depending on the interpretation of the recitation "a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO: 1 or 3 of an AKAP10 allele..." the claim may lack description. Because it is unclear whether the claim is directed to a sequence of nucleotides that specifically hybridizes adjacent to an AKAP10 allele, the specification has only described a single allele within the scope of the claims. The description of this single variant is not representative of all AKAP10 alleles. The nature of variants is such that the indication of a single variant allele is not representative of unknown alleles. The variant structures, in the present state of the art, of one variant does not provide guidance to the structure of others.

Claim 44 is directed to a cell comprising a nucleic acid that encodes a human AKAP10 variant protein or portion that exhibits a biological activity of the full length variant protein wherein the AKAP10 variant protein or portion thereof comprises valine at position corresponding to the position of amino acid residue 646 of SEQ ID NO: 2. The specification has described a single human AKAP10 variant protein, namely a substitution at amino acid position 646 of SEQ ID NO: 2. The specification does not particular provide any additional variant proteins that exhibit a biological activity of the variant protein. The specification fails to provide any biological activity information for the variant protein to constitute a function, therefore, determining whether the portion exhibits biological activity has not been described. Furthermore, the claim encompasses additional mutations, splice variants and transitions which have not been

described in the instant specification. The nature of variants is such that the indication of a single variant allele is not representative of unknown alleles. The variant structures, in the present state of the art, of one variant does not provide guidance to the structure of others.

Therefore, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Response to Arguments

The response traverses the rejection. With respect to Claims 6-8, 69, the response asserts that the claimed nucleic acid molecules comprise a common conserved element. This argument has been thoroughly reviewed, but is not found persuasive because the claim is not limited to fragments of SEQ ID NO: 3, for example. The claims encompass splice variants of AKAP10-5, polymorphic sequences, full length genes or homoglous sequence which have not been described and applicant was not in possession of. There is no requirement in the claims that the sequence is a particular fragment of a sequence or has any particular function. The claims broadly encompass each of these variants which applicant was not in possession of at the time of filing. One of skill in the art would have concluded that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim. The

written description requirement is directed to the possession of the applicant of the claimed subject matter.

The response argues that "one of skill in the art would readily understand that as long as the nucleic acid molecule includes at least 16 contiguous nucleotides of SEQ ID NO: 3 that contain 5 contiguous nucleotides the region is conserved. This argument has been reviewed, but not deemed persuasive because upon a simple blast search of 16 contiguous nucleotides beginning with 2073, a hit was found for chromosome 5, namely AC024579.5, Homo sapiens chromosome 5 clone CTD-2582M21, complete sequence of length = 149870, matches at 2123-2138. Arguments that this length is "statistically unique in the genome is therefore, not persuasive" since it is clear that the 16 mer occurs on chromosome 5, which is not chromosome 17 where the AKAP10 gene is located. Furthermore, possession is not related to statistically uniqueness in a genome. Possession is whether a representative number of species within the genus have been described.

Claim 11 has been amended to require 16 nucleotides and high stringency conditions. The response further argues that the skilled artisan would understand that a corresponding position to be at least 95% identical with the reference sequence. As seen in Written Description Example 9, claims drawn to cDNA which hybridize under highly stringent conditions, and provide a function may be found to be described. However, the instant claims are drawn to partial sequences, and lack any particular function. The specification specifically indicates that the concept of corresponding does not mean identity with the flanking sequences. Therefore, the claims encompass large

numbers of nucleic acids which have neither been reduced to practice or described. As discussed above, the "statistically uniqueness" of the molecule is not relevant to the issue of whether applicants have disclosed and were in possession of a representative number of species within the genus. The response asserts that there must be sufficiently complementarily to be able to hybridize under high stringency conditions. This argument has been thoroughly reviewed, but is not found persuasive because as specifically pointed out in Example 9 of the guidelines, structure function relationship is required for hybridization language to meet written description. The asserted functions of the nucleic acid are not functions, but further define the structure. Hybridization language is not function, but rather is more structure. The guidelines are directed to hybridization conditions in combination with the *coding* function of DNA. Variants, splice variants, homologues, for example would still function to hybridize to the selected sequences. There is no particular function of the encoded protein (i.e. coding function of DNA), like the adenylate cyclase activity of Example 9.

The rejection as it applies to Claim 44 has been traversed. The response asserts that that the protein must contain a Val at residue 646 of SEQ ID NO: 2. This argument has been thoroughly reviewed, but is not found persuasive because the claim does not require SEQ ID NO: 2, but merely requires a AKAP10 variant protein with a valine. The protein may contain additional variants, mutations, truncations which have not been described. One of skill in the art would have concluded that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the

claim. The response filed May 12, 2004, asserts that biological activity of an AKAP10 protein is defined in the specification. This argument has been thoroughly reviewed, but is not found persuasive because the definition is not limited to any particular function, but leaves the definition open to be interpreted broadly. The definition explicitly states that the definition is not limited to the definition. In the event that applicants wish to be limited to such a biological activity, the claims could be amended to require such activity. However, it is unclear which and whether the disclosed variants have such an activity, since the specification does not appear to specifically demonstrate the activity. The response asserts that the claims are not limited to additional variants, mutations or truncations. The claims however, encompass these embodiments which have not been described nor in possession of the specification at the time the invention was made. The arguments directed to the ability of the nucleic acid to bind to PKA or to an R-subunit within PKA is not a function of the coding DNA as required for function. This is merely more binding or hybridization language.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-2, 6-8, 11, 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Kwok (NCBI Single Nucleotide Polymorphism, ss266958, rs203462, June 30, 2000).

Kwok teaches a SNP in the AKAP10 gene which causes a change from A to G. The SNP sequence of Kwok encodes a polypeptide fragment of SEQ ID NO: 2, including a Val. The polynucleotide of Kwok comprises nucleotides 2023-2120 of SEQ ID NO: 3 (limitations of Claims 6-8, 15). The nucleic acid of Kwok comprises a region of about 100 contiguous nucleotides which are 100% identical with SEQ ID NO: 3, therefore, the nucleic acid of Kwok would hybridize to SEQ ID NO: 3 (limitations of Claim 11). Since Kwok teaches each limitation of the instant claims, Kwok anticipates the claims.

10. Claims 11, 17-18 rejected under 35 U.S.C. 102(b) as being anticipated by Chatterjee et al. (Genbank Accession Number AF037439, December 1997).

Chatterjee et al. (herein referred to as Chatterjee) teaches a nucleic acid comprising 2363 bp from the homo sapiens protein kinase A anchoring protein mRNA. The probe comprises at least 30 contiguous nucleotides that specifically hybridize under high stringency conditions adjacent to and spanning a polymorphic region of SE QID NO: 1. Positions 1-2072 and 2074-2363 of both the instant SEQ ID NO: 1 and Chantterjee are 100% identical. The probe of 2363 nucleotides in length will hybridize to under high stringency conditions adjacent to and spanning SEQ ID NO: 1, position 2073. The single mismatch between the two sequences would not prevent hybridization

under high stringency conditions. Therefore, since Chatterjee teaches all of the limitations of the instant claims, Chatterjee anticipates the claimed invention.

Allowable Subject Matter

11. Claims 3-5, 45-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter. The claims are drawn to an isolated nucleic acid molecule comprising nucleotides 138-2126 of SEQ ID NO: 1 with a G, T or C at position 2073. The prior art does not teach a sequence comprising 138-2126 of SEQ ID NO: 1 with a G, T or C at position 2073. The nucleic acid of AKAP10-5 variant is associated with left ventricular function. The specification teaches that the variant nucleic acid is more frequent in individuals with abnormal LV ejection fraction. LV ejection fraction is a strong predictor of cardiovascular mortality. Further, the specification teaches that the variant is associated the cardiovascular disease in men over the age of 50. Thus, the nucleic acid would be useful for predicting LV ejection fraction or cardiovascular disease in men over the age of 50.

Conclusion

12. No claims allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Goldberg

Jeanine Goldberg
Patent Examiner
July 20, 2004